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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,474

04/07/2004

Preeti Lal

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7560

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FOLEY AND LARDNER LLP
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/820,474	Applicant(s) LAL, PREETI ET AL.	
	Examiner Robert Landsman, Ph.D.	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 August 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 56-64.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER


11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
 13. ☒ Other: See Continuation Sheet.


 Robert Landsman
 Primary Examiner
 Art Unit 1647

Continuation of 13. Other: Applicants argue that the specification describes that the nucleotide sequence, SEQ ID NO: 177, encoding the protein of SEQ ID NO: 43, is expressed in gastrointestinal tissues and relates to cancer and inflammation. Applicants also argue that the polynucleotide represented by SEQ ID NO: 177 was isolated from diseased sigmoid colon tissues. Therefore, the disclosure of the original specification is consistent with and corroborated by the teachings of Hogan et al. (J. Allergy Clin Immunol. 2006, 118:257-268; previously submitted) that RELM-beta protein is constitutively expressed in colon and that it has a central role in regulating colonic inflammation.

These arguments have been considered, but are not deemed persuasive. This asserted utility is not specific or substantial. With the exception of a few housekeeping genes, all naturally occurring polypeptides have a tissue specific pattern of expression, and thus virtually any naturally occurring polypeptide can be used in tissue typing. Thus, the asserted utility is not specific to SEQ ID NO:43. The fact that the polynucleotide/polypeptide was isolated from cancer tissue does not demonstrate its utility, or that it is involved in cancer. Similarly, Applicants have not demonstrated what role the protein has in regulating colonic inflammation and in which manner (upregulated or downregulated) the protein should be modulated. Furthermore, while Applicants' assert that the protein of the invention is consistent with Hogan et al., the specification never identifies this protein as a RELM-beta. Due to the length of the specification, it is suggested that Applicants point out exactly where in the specification this "consistency" is found.

The claims also remain rejected under 35 USC 112, first paragraph, since the invention does not possess utility as discussed in the previous Office Action. Furthermore, Applicants have not provided a functional limitation in the claims reciting "95%," only a structural limitation.


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER